



**ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Dear Sir:

Applicant respectfully requests a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1-4, 8-13 and 21-24 remain pending in this application. Claims 1-4, 10, 11 and 21 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,939,350 ("Phan"). Claims 9, 12, 13 and 22-24 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Phan in view of U.S. Patent No. 6,366,813 ("DiLorenzo"). Applicant respectfully disagrees.

**Claim Rejections under 35 U.S.C. §102(e)**

Independent claims 1 and 10 each recite an apparatus for delivering acoustic energy to a target site. In particular, claim 1 recites an apparatus for delivering acoustic energy to a target site, the apparatus including a catheter; and a transducer secured to the catheter, the transducer having a surface configured to be placed on a tissue, the catheter comprising a channel located adjacent the transducer and adapted for carrying cooling fluid. Claim 10 recites an apparatus for delivering acoustic energy to a target site, the apparatus including a catheter having a distal end, a proximal end, and a lumen extending there between; a transducer secured to the catheter distal end, the transducer having a surface configured to be placed on a tissue region and configured to deliver acoustic energy to the tissue region; and means for cooling the catheter distal end. Independent claim 21 recites a method for delivering acoustic energy to a tissue region within a body, including the steps of introducing a catheter carrying a transducer into a body, the transducer having a surface; placing the surface of the transducer on the tissue region; delivering acoustic energy to the tissue region; and cooling a tissue adjacent or within the tissue region to reduce heat that is generated from the delivered acoustic energy.

In contrast, Phan discloses several embodiments of surgical probes with shafts 102 that consist of a central mandrel 110 surrounded by an electrically non-conductive outer structure 112. Col. 5, lines 23-25. Phan also discloses methods of using such surgical probes to form lesions. Col. 5, line 46 – Col. 6, line 33. Applicant respectfully points out that Final Office Action (FOA) has erred in stating on page 2 that Phan's

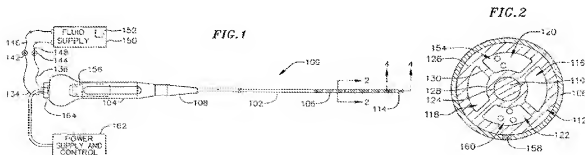
probe discloses a method and system for delivering acoustic energy to a target site, wherein the system includes, inter alia, "a catheter".

Phan explicitly distinguishes "shafts in accordance with [its] inventions" from "the shafts of conventional catheters". Col. 5, lines 56-57, see also Col. 6, lines 19-27 and 43-47. The shafts 102 of Phan's surgical probe 100 are formed from a central mandrel 110 surrounded by an electrically non-conductive outer structure 112. Col. 5, lines 23-25. Fluid inlet and outlet lumens 116 and 118 are formed into the solid outer structure 112. Col. 9, lines 23-27.

In contrast, the catheters of the instant application include a hollow elongate member 402, having a lumen 408 extending between distal and proximal ends 404, 406. Para. 36. A transducer 420 is secured to the distal end 404 and fluid delivery lumens 410, 411 are located within a wall of the elongate member 402. Id.

Phan, which provides details about only solid surgical probes, does not disclose (1) how electrodes and cooling structures would be integrated into or used with hollow catheters or (2) methods of using such catheters. Regarding claim 1, Phan does not disclose an apparatus for delivering acoustic energy to a target site including a catheter; and a transducer secured to the catheter, the catheter comprising a channel located adjacent the transducer and adapted for carrying cooling fluid. Regarding claim 10, Phan does not disclose an apparatus for delivering acoustic energy to a target site including a catheter having a distal end, a proximal end, and a lumen extending there between; a transducer secured to the catheter distal end; and means for cooling the catheter distal end. Regarding claim 21, Phan does not disclose a method for delivering acoustic energy to a tissue region within a body, including the step of introducing a catheter carrying a transducer into a body.

By way of illustration, see Figures. 1 and 2 of Phan:



Conversely, see Figure 4 of the present application:

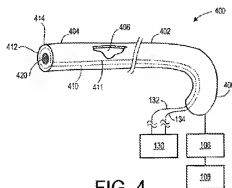


FIG. 4

For at least the reasons stated above, Applicant respectfully submits that each and every element and act set forth by independent claims 1, 10 and 21, and claims 2-4 and 11, which depend from claims 1 and 10 respectively, are not found in Phan. Applicant also respectfully submits that accordingly, the FOA does not support a prima facie case of anticipation and as such respectfully requests withdrawal of the §102(e) rejections of these claims.<sup>1</sup>

#### **Claim Rejections-35 U.S.C. §103**

Claims 9, 12, 13 and 22-24 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Phan in view of DiLorenzo. Applicant respectfully disagrees.

Preliminarily, Applicant respectfully submits that the teachings of these references are not properly combinable to achieve the claimed inventions, thus, they do not support a prima facie case of obviousness. As discussed above, Phan explicitly distinguishes "shafts in accordance with [its] inventions" from "the shafts of conventional catheters". Col. 5, lines 56-57, see also Col. 6, lines 19-27 and 43-47. As such, there can be no "reason that would have prompted a person of ordinary skill in the relevant field to combined the elements in the way the claimed new invention does," as required by KSR. Nor can be any "apparent reason to combine the known elements in the fashion claimed," as required by the BPAI decision in Ex Parte Whalen.

Regarding claim 9, which depends from claim 1, Phan does not disclose an apparatus for delivering acoustic energy to a target site including a catheter comprising

<sup>1</sup> Claim 8 is withdrawn from examination as being directed to a non-elected species, but respectfully requested to be reinstated and allowed upon allowance of respective generic claim 1 from which it depends.

a channel located adjacent the transducer and adapted for carrying cooling fluid. While DiLorenzo discloses a neurological control system for modulating activity of the nervous system or any structure interfaced thereto, but it does not disclose any catheter cooling system. Abstract.

Regarding claims 12 and 13, which depend from claim 10, Phan does not disclose an apparatus for delivering acoustic energy to a target site including a catheter having means for cooling the catheter distal end. As discussed above, DiLorenzo does not supply this missing limitation. Further, claims 9 and 13 also require an acoustic energy sensor secured to the catheter. While DiLorenzo discloses head-mounted 11, proximal 27, enclosure-mounted 35, and distal acoustic sensors 19, DiLorenzo does not disclose acoustic energy sensors secured to catheters. Col. 14, lines 39-44.

Claims 23 and 24 require the act of sensing reflected acoustic signals associated with delivered acoustic energy and analyzing the reflected acoustic signals. While DiLorenzo discloses using acoustic sensors to monitor vibratory characteristics, DiLorenzo does not disclose sensing reflected acoustic signals associated with delivered acoustic energy and analyzing the reflected acoustic signals. Col. 8, lines 52-55.

For at least these reasons, Applicant respectfully submits that the Examiner has not set forth a prima facie case that claims 9, 12, 13 and 22-24 are unpatentable under 35 U.S.C. §103(a), as being obvious over Phan in view of DiLorenzo.

### **CONCLUSION**

For the reasons set forth above, Applicant respectfully submits that currently pending claims are patentable over the cited prior art. A notice of allowance is respectfully requested.

Respectfully submitted,  
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Reg. No. 37,104